JUL 1 9 2000

K001511

Summary of Safety and Effectiveness

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Manufacturer:

A.R.C. Laser AG
St. Gallerstrasse 161
CH-8645 Jona
Switzerland

Submitter/Contact Person:

Daniel Hoefer
A.R.C. Laser Corporation
2417 South 3850 West
Salt Lake City, UT 84120
(801) 972 1311, FAX (801) 972 5251

Name of Device:

Trade Name: Q-Las Ophthalmic Laser System

Classification Name: Nd:YAG laser for posterior capsulotomy and peripheral Iridotomy.

Predicate Devices:

HGM Penacle (K931499), Laserex LQ2106, Nidek YC-1100 (K893987).

Description of Device:

The Q-Las 10 Ophthalmic Laser is an Nd:YAG photodisruptor intended for use in posterior capsulotomy, pupillary membranectomy, and peripheral iridotomy procedures. It is designed for integration with a Haag-Streit BQ/BM slit lamp biomicroscope, and is comprised of three modules. They are the power module, the control module and the laser module.

The laser system produces short duration pulsed 1064 nm laser output with low energy and high power. When focused, the laser pulse is capable of producing

irradiance sufficient to cause optical breakdown and subsequent tissue disruption. The Q-Las 10 Ophthalmic Laser System precisely controls delivery of Nd:YAG pulses to perform non-invasive posterior capsulotomy and peripheral iridotomy procedures. The electical requirement is 100-240 VAC, 3.0 Amps, 47-63 Hz. The system is convection air-cooled.

The system is designed to comply with 21 CFR 1040.10 and 1040.11, ANSI 136.1 (1993), and IEC 60825-1 (1998). It also complies with IEC 60601 standards for Electrical Medical Devices, including IEC 60601-1, IEC 60601-1-1, IEC 60601-2, and IEC 60601-2-22.

Intended Use:

The Q-Las 10 is intended for intended for disruption of the posterior membrane or the iris via optical breakdown. It is indicated for use in posterior capsulotomy, pupillary membranectomy and peripheral iridotomy.

Technological Characteristics:

The Q-Las 10 consists primarily of a power supply, control module, laser head, and delivery optics. The flashlamp-pumped, q-switched Nd:YAG system produces laser pulses of wavelength 1064 nanometers, duration 4 nanoseconds, and energy per pulse of 0.5 to 10.0 millijoules. The system optics focus the beam to a spot size of 10 microns, resulting in irradiances sufficient to cause optical breakdown. In burst mode, the system may produce either 2 or 3 pulses in sequence, delivering a total energy of up to 25 milliwatts.

The aiming system utilizes dual 650 nm red-diode beams. An adjustable focus offset of 0-300 microns posterior permits the user to optimize tissue disruption without damaging implants or adjacent structures. The system requires 100-240 VAC 50/60 Hz power input.

Device Comparison:

The Q-Las 10 and the predicate devices, including the HGM Penacle (K931499), the Nidek YC-1100 (K893987), and the Laserex LQ2106 are each intended for photodisruption of ocular tissue. Each utilizes an integrated slit lamp biomicroscope for the delivery of 1064 nm laser energy, emitted from a Q-switched Nd:YAG laser. Laser beam parameters and focusing (cone angle) are the same or equivalent in all of the devices. Each uses a dual red aiming laser for targeting the treatment site. Each device has an adjustable posterior focus offset. The laser controls, power requirements, materials, method of manufacture, indications and labeling are all the same or equivalent.

Conclusion:

The Q-Las 10 Ophthalmic Laser System is designed and manufactured to applicable standards. It raises no new questions of safety and effectiveness and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

A.R.C. Laser AG
c/o Mr. Daniel Hoefer
Regulatory Affairs Manager
A.R.C. Laser Corporation
2417 South 3850 West
Salt Lake City, Utah 84120

Re: K001511
Trade Name: Q-Las 10 Ophthalmic Photodisruptor
Regulatory Class: II
Product Code: GEX
Dated: May 11, 2000
Received: May 15, 2000

Dear Mr. Hoefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Pending K001511

Device Name: Q-Las 10 Ophthalmic Photodisruptor

Indications For Use:

1. Posterior capsulotomy
2. Pupillary membranectomy
3. Peripheral iridotomy

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001511

Prescription Use ✓ **OR Over-The-Counter Use** ____
(Per 21 CFR 801.109)

(Optional Format